UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TORPHARM, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
TOMMY G. THOMPSON, *et al.*	)	
	)	
Defendants,	)	**Civil Action No. 03-0254 (ESH)**
	)	
and	)	
	)	
PURPAC PHARMACEUTICAL CO.,	)	
	)	
Intervenor-Defendant	)	
	)	

MEMORANDUM OPINION

This is the latest installment in the long-running battle to determine which will be the first company permitted to market a generic version of the drug gabapentin. Competing for this privilege – and, more importantly, for the statutory right to sell the drug for 180 days free from generic competition – are plaintiff TorPharm, Inc. ("TorPharm") and intervenor-defendant Purepac Pharmaceutical Co. ("Purepac"). Originally, the Food and Drug Administration ("FDA") refused to approve Purepac's application because it failed to include what the agency believed to be the proper certification (a "paragraph IV certification") regarding a method-of-use patent covering gabapentin owned by the Warner-Lambert Company ("Warner-Lambert"). However, on December 16, 2002, this Court vacated that decision, and ordered the FDA to accept the alternative patent statement (a "section viii statement") that Purepac had submitted with its application. *See Purepac Pharmaceutical Co. v.*

Thompson, 238 F. Supp. 2d 191 (D.D.C. 2002). At the same time, the Court declined to go further and to forbid the agency from approving the application submitted by TorPharm, which did not contain the section viii statement filed by Purepac, but instead included a paragraph IV certification. The Court left the FDA free to resolve the "delicate question" of whether to approve TorPharm's application, and thus potentially to allow the company to share with Purepac the limited period of exclusivity for the sale of generic gabapentin. *See id*. at 211-12.

On remand, TorPharm urged the FDA to do just that, but the agency was not persuaded. The FDA ruled instead that – in light of its understanding of the statute, this Court's decision in *Purepac*, and other factual developments – a paragraph IV certification was inappropriate for the patent in question. The agency further concluded that Purepac was the first gabapentin applicant to have submitted a generic application with a valid paragraph IV certification (which related to another patent covering the drug). Based on these findings, the FDA announced that Purepac, and only Purepac, would be entitled to the 180-day exclusivity period. Arguing that these decisions are unreasonable and illegal, TorPharm brought this action, seeking a preliminary injunction to block the FDA's grant of exclusivity to Purepac and to compel the agency to bestow that privilege on TorPharm instead.

Pursuant to FED. R. CIV. P. 65(a)(2), the Court has consolidated the preliminary injunction motion with a final decision on the merits. TorPharm's motion, and the FDA's response thereto, will thus be treated as cross motions for summary judgment. Based on the pleadings, and for the reasons given below, the Court will deny plaintiff's motion, and enter judgment on behalf of the agency. In concluding that Purepac was the first company to present an effective paragraph IV certification, the FDA did not, as TorPharm insists, disregard clear statutory language, but rather reasonably filled in a

textual gap. Moreover, the agency's rejection of TorPharm's certification represented an appropriate application of administrative discretion that cannot be characterized as arbitrary and capricious.

BACKGROUND

The complex legal and factual background to this case is set out at length in the Court's previous Memorandum Opinion and need not be exhaustively retold here. *See Purepac*, 238 F. Supp. 2d at 193-201. Like its predecessor, this case involves the Hatch-Waxman Amendments to the Food, Drug, and Cosmetic Act ("FDCA"), which have been codified at 21 U.S.C. § 355. These amendments were designed to streamline the process by which generic versions of drugs already approved by the FDA are brought to market. They allow a generic drug manufacturer to piggyback on the detailed "New Drug Application" ("NDA") filed by the manufacturer of the brand-name version of the drug (the so-called "pioneer" or "innovator") during the original approval process. Under the Hatch-Waxman Amendments, a would-be generic manufacturer can file a much less elaborate document, called an Abbreviated New Drug Application ("ANDA"), which relies on the FDA's previous determination that the drug is safe and effective.

While the ANDA process makes it significantly less expensive and time-consuming to gain approval of generic drugs, the Hatch-Waxman Amendments also sought to protect the interests of patent owners, whose valuable rights in the pioneer drug could be threatened by the marketing of cheaper, generic versions of their patented innovations. To this end, every ANDA must contain information about the patents protecting the brand-name drug, and the expected effect of the generic drug on those patents. One important purpose of this requirement is to give notice, if necessary, to the

patent holder so that any legal disputes regarding the scope of the patent and the possibility of infringement can be resolved as quickly as possible. The source for this patent information is typically the "Orange Book" (a shorthand name for the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations"), in which the agency publishes the patent information it receives from brand manufacturers in their NDAs. *See* 21 U.S.C. § 355(b)(1) (requiring those seeking approval for new drugs to file with the FDA "the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" and requiring the agency to publish this information).

The ANDA applicant has several possible vehicles by which to discharge its patent notification responsibilities. With respect to "each patent which claims the listed [*i.e.* FDA-approved] drug . . . or which claims a use for such listed drug for which the applicant is seeking approval," the ANDA must "certify" (I) that no patent has been filed with the FDA; (II) that the patent has expired; (III) that the patent will expire on a date certain; (IV) that the patent is invalid or will not be infringed by the generic drug. 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV); 21 C.F.R. § 314.94(a)(12)(i). The last of these – the so-called "paragraph IV certification" – is the most complicated. Given its importance to the present case, several points about this certification require further elaboration. The first is its notice requirement. The statute mandates that a generic drug applicant who uses a paragraph IV certification "shall include in the application a

statement that the applicant will give the notice required by clause (ii)"[1/] both to the patent owner and to the holder of the NDA. 21 U.S.C. § 355(j)(2)(B)(i). Where an ANDA is amended to include a paragraph IV certification, the statute requires that this notice "shall be given when the amended application is submitted." 21 U.S.C. § 355(j)(2)(B)(iii) (hereinafter, "the notice provision").

Once notice is received, the patent owner has 45 days in which to bring an infringement action against the ANDA applicant. Such actions are brought under 35 U.S.C. § 271(e)(2)(A), which makes it an act of infringement to submit an ANDA "for a drug claimed in a patent or the use of which is claimed in a patent." Thus, whenever a generic applicant includes a paragraph IV certification in its ANDA, that act itself permits the brand manufacturer to initiate an immediate patent infringement suit even though the generic manufacturer has not yet marketed the drug. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990). If no action has been commenced at the end of this 45-day period, the FDA may approve the application effective immediately. *See* 21 U.S.C. § 355(j)(5)(B)(iii). If an infringement action is filed, however, the agency may not approve the application for 30 months from the date the notice was received, or until the patent dispute is judicially resolved, whichever is shorter. *Id.*; s*ee generally Am. Bioscience, Inc. v. Thompson*, 243 F.3d 579, 580 (D.C. Cir. 2001).

Finally, as an incentive to generic drug applicants willing to risk litigation in order to challenge a pioneer manufacturer's patent, the statute provides that the first applicant whose ANDA included a

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[1/] Clause (ii) specifies that such notice must, among other requirements, "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." 21 U.S.C. § 355(j)(2)(B)(ii).

paragraph IV certification is entitled to a 180-day period of market exclusivity. The onset of this period is triggered by either the first commercial marketing of the drug or by a decision of a court finding the patent that is the subject of the paragraph IV certification invalid, unenforceable, or not infringed, whichever comes first. *See* 21 U.S.C. § 355(j)(5)(B)(iv); 21 C.F.R. § 314.107(c). During this window, the FDA may not make effective the approval of any other ANDA for the drug in question that contains a paragraph IV certification. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (hereinafter "the exclusivity provision").[2/] This provision allows the first mover to enjoy a brief duopoly in which the only other authorized seller of the drug is the brand manufacturer. *See SmithKline Beecham Corp. v. Apotex Corp*., 2003 WL 728889, at *10 (N.D. Ill. March 3, 2003).

There is, however, an alternative to the paragraph IV certification, known as a "section viii statement," which an ANDA applicant may use where the patent in question is a "method of use patent which does *not* claim a use for which the applicant is seeking approval under this subsection. . . ." 21 U.S.C. § 355(j)(2)(A)(viii) (emphasis added).[3/] A section viii statement avers that the patent in question has been listed, but does not claim a use for which the applicant seeks FDA approval. An applicant proceeding by way of section viii need not provide formal notice to the patent owner and

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[2/] By regulation, the FDA has clarified that the exclusivity provision delays the approval only of later-submitted ANDAs containing a paragraph IV certification to *the same patent* to which a previous applicant has already offered such a certification. *See* 21 C.F.R. § 314.107(c)(1).

[3/] The FDA regulations implementing this statutory provision decree that a section viii statement is to be used where patent information has been submitted "for a patent claiming a method of using the listed drug, and the labeling for the drug product for which the applicant is seeking approval does not include any indications that are covered by the use patent. . . ." 21 C.F.R. § 314.94(a)(12)(iii)(A).

NDA holder, does not necessarily face an infringement action under 35 U.S.C. § 271(e)(2)(A),[4/] and does not face a mandatory 30-month stay should the patent owner sue. At the same time, however, section viii does not entitle the successful generic applicant to any period of exclusivity. Accordingly, as an alternative to paragraph IV certifications, section viii statements offer generic drug manufacturers a diminished set of both risks and rewards.

Of great significance to the present case is the FDA's long-held position that the circumstances in which a section viii statement may be used and those in which a paragraph IV certification is appropriate do not overlap. *See* Abbreviated New Drug Application Regulations, Patent and Exclusivity Provisions, 59 FED. REG. 50,338, 50,347 (Oct. 3, 1994) (hereinafter "*ANDA*

[4/] A recent Federal Circuit decision limits the use of 35 U.S.C. § 271(e)(2)(A) in situations where a section viii statement might be appropriate. In *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1354-55 (Fed. Cir. 2003), the court held that it is not an act of infringement under that provision "to submit an ANDA for approval to market a drug for a use when neither the drug nor that use is covered by an existing patent, and the patent at issue is for a use not approved under the NDA." In other words, § 271(e)(2)(A) applies only to actions for infringement of "controlling use patents," *i.e.* patents that claim an *approved* use of a drug. *Id*. at 1362. Thus, under *Warner-Lambert*, an ANDA applicant who is not seeking approval for the use covered by the patent in question, where that use has not been approved by the FDA, is not subject to suit under § 271(e)(2)(A).

However, a subsequent Federal Circuit decision, while following *Warner-Lambert* as binding precedent, signaled sharp disagreement with its conclusion. *See Allergan, Inc. v. Alcon Labs., Inc.*, 2003 WL 1572020 (Fed. Cir. March 28, 2003). Indeed, after a *per curiam* opinion applying *Warner-Lambert* to the facts at hand, all three members of the panel wrote or joined separate opinions criticizing the earlier case's interpretation of § 271(e)(2)(A). Specifically, Judge Schall (joined by Judge Clevenger) emphasized the plain language of the provision, which in his view, authorizes an induced infringement action where *any* use, whether approved or not, of the drug for which the ANDA seeks approval is covered by a existing patent. *Id*. at *20 (Schall, J., concurring). While the third judge, Judge Linn, did not join Judge Schall's opinion, he expressed similar views about the proper construction of § 271(e)(2)(A). *See id*. (Linn, J., concurring) ("In my opinion, the court in *Warner-Lambert* has ventured beyond our interpretive role and, in interpreting the complex statutory scheme before it, has allowed its policy choices and its evaluation of the legislative history – reasonable as they may be – to override the terms of the statute chosen by Congress.").

Rulemaking") (noting that "the two provisions . . . are not overlapping, and an applicant does not have the option of making a certification under [paragraph IV] in lieu of, or in addition to, a statement under [section viii]."). Therefore, in the agency's view, a paragraph IV certification and a section viii statement are mutually exclusive alternatives. The factor that determines which is proper is whether the use patent at issue actually claims a use for which the generic applicant is seeking approval. If it does, a paragraph certification is required; if not, the ANDA should include a section viii statement. (Administrative Record ["A.R."], tab 18 at 4.)

This case involves rival ANDAs submitted for the drug gapapentin, which is sold under the brand name Neurontin®. Pfizer, by assignment from Warner-Lambert, holds the NDAs for this drug, which the FDA approved in 1993 (in capsule form) and in 1998 (in tablet form) for the treatment of epilepsy.[5/] In connection with these applications, Warner-Lambert submitted a variety of patent information regarding gabapentin, including two method-of-use patents covering the drug. The first is U.S. Patent No. 4,087,544 ("the '544 patent"), which claims a method of using gabapentin to treat epilepsy, and has now expired. The second, U.S. Patent No. 4,084,479 ("the '479 patent"), claims a method of using the drug to treat neurodegenerative diseases.[6/] This patent is set to expire on January 2, 2010. A third patent relevant to this case, a drug composition patent, is U.S. Patent No. 6,054,482

[5/] In mid-2002, the agency approved gabapentin for the treatment of postherpetic neuraligia, a use that is not relevant to the present case.

[6/] The FDA has never approved gabapentin for the treatment of neurodegenerative diseases, which, therefore, is considered an "off-label" use. Drug companies are forbidden by law from promoting their products for such unapproved uses, although it is neither uncommon nor illegal for treating physicians to do so. *See Ortho Pharm. Corp. v. Cosprophar, Inc.*, 828 F. Supp. 1114, 1117 & n.5 (S.D.N.Y. 1993).

("the '482 patent"), which Warner-Lambert submitted to the FDA on April 25, 2000. All three of these patents, along with one other covering the drug,[7/] were listed in the Orange Book. In keeping with FDA practice, however, the '544 patent was removed from the book when it expired on July 16, 2000.

In March 1998, Purepac submitted an ANDA seeking permission to market generic versions of gabapentin capsules for the treatment of epilepsy. In this application, Purepac included a section viii statement regarding the '479 patent, which appeared to claim a use (the treatment of neurodegenerative diseases) for which the company was not seeking approval, and indeed could not have sought approval through the ANDA process. This application also contained a paragraph IV certification to the '476 patent and a paragraph III certification to the '544 patent. On May 26, 2000, FDA received from Purepac an amendment to its application that included a paragraph IV certification for the newly submitted '482 patent.

The rival gabapentin ANDA at issue in this case was filed by TorPharm on April 20, 1998. Like Purepac's, this application contained a paragraph IV certification to the '476 patent and a paragraph III regarding the '544 patent. However, with respect to the '479 patent, TorPharm hedged its bets and included both a section viii statement *and* a paragraph IV certification. On June 16, 2000, the FDA received TorPharm's amended paragraph IV certification regarding the '482 patent.

These applications have triggered several rounds of patent litigation. First, Warner-Lambert brought suit against Purepac in New Jersey alleging infringement of both the '476 and '479 patents.

[7/] U.S. Patent No. 4,894,476 ("the '476 patent") is a drug substance patent.

That case is still pending, though the 30–month stay triggered by this suit has long since expired. Then, on July 14, 1998, Warner-Lambert sued TorPharm in Illinois, alleging infringement of the same patents. In March 2001 and September 2001, the district court granted summary judgment in favor of TorPharm on both patents respectively; Warner-Lambert appealed only the decision regarding the '479 patent to the Federal Circuit. On January 16, 2003, that Court affirmed, holding that because the '479 patent did not claim an approved use of gabapentin, Warner-Lambert could not sue for infringement under 35 U.S.C. § 271(e)(2)(A). *See Warner-Lambert*, 316 F.3d at 1362. Finally, on July 20, 2000, Warner-Lambert sued both Purepac and TorPharm in connection with their paragraph IV certifications to the '482 patent. The Judicial Panel on Multidistrict Litigation has consolidated these suits for pretrial proceedings in New Jersey, and they are ongoing. While no decision regarding the '482 patent has issued, the 30-month stays relating to this litigation have now expired. Accordingly, at present, no litigation-related stays prevent the FDA from approving the ANDAs submitted by Purepac or by TorPharm.

The confusion about whether a section viii statement or a paragraph IV certification was appropriate for the '479 patent spawned separate litigation, which continues in the present case. As noted, Purepac and TorPharm took different approaches to this patent in their ANDAs, the former using only a section viii statement, while the latter used both. Initially, the FDA took the position that only a paragraph IV certification was proper, and therefore disregarded TorPharm's section viii statement. Furthermore, in April 2002, the FDA wrote two letters to Purepac informing the company that a section viii statement was improper for the '479 patent and that to secure agency approval for its ANDAs, it would have to submit a revised certification under either paragraph III or IV. (A.R., tabs

30-31.) Purepac refused to amend its application, and instead sued the FDA in this Court on August 20, 2002, challenging the agency's position that a section viii statement was impermissible.

On December 16, 2002, the Court ruled in favor of Purepac, holding that "the FDA's decision not to approve Purepac's ANDAs because they contained section viii statements regarding the '479 patent impermissibly disregarded both Warner-Lambert's and the agency's own understanding of the coverage claimed by that patent." *Purepac*, 238 F. Supp. 2d at 212. Patent information had been submitted for the '479 patent, but that patent did not claim, or purport to claim, a use for which Purepac was seeking approval.[8/] As such, the Court determined that a section viii statement was appropriate as to that patent, and thus vacated the FDA's contrary conclusion. The case was then remanded to the agency with instructions to accept Purepac's application containing the section viii statement.

At the same time, however, the Court declined to go further and require the agency to reject TorPharm's paragraph IV certification to the '479 patent. While the Court noted the FDA's prior statements that paragraph IV certifications and sections viii statements are mutually exclusive alternatives, it also observed that the agency had not pressed this view in the context of the Purepac litigation:

[A]t oral argument, the agency stated that it has not taken a definitive position as to

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[8/] In reaching this conclusion, the Court alluded to a letter submitted to the Court by Pfizer (on behalf of Warner-Lambert) on December 13, 2002, in which the company asserted that it had never represented or intended to represent to the FDA that the '479 patent covered the approved use of gabapentin for epilepsy. The Court did not rely on this letter, but merely noted that it "confirmed what should have been obvious to the agency: that Warner-Lambert's patent listings represented only that the '479 patent claimed the use of treating neurodegenerative diseases, and did not suggest that the patent covered the treatment of epilepsy." *Purepac*, 238 F. Supp. 2d at 209 n.25.

> whether equitable considerations might ultimately persuade it to allow two applicants to submit a certification and a statement, respectively, with respect to the same patent. As such, the FDA has not decided whether it could, or would, approve TorPharm's application with a paragraph IV certification to the '479 patent even if the Court were to direct the agency to accept Purepac's application with a section viii statement. Because the agency has not done so, and because Purepac has not demonstrated that such a result is barred by the terms of the statute or precluded by existing FDA regulations, the Court will leave this delicate question for the agency to resolve in the first instance.

Id. at 211. This decision set the stage for the present round of litigation.

For, on remand, the agency gave Purepac what it had sought all along: the exclusive right to sell gabapentin free from generic competition for 180 days. After soliciting comments from all gabapentin ANDA applicants regarding the effect of the *Purepac* decision, the FDA made that decision in a letter issued on January 28, 2003 (the "Decision Letter"). (A.R., tab 18.) This conclusion was based on the agency's determination that Purepac had been the first company to offer an approvable ANDA containing a proper paragraph IV certification. The FDA's analysis focused on two patents: the '479 patent that was at the heart of the *Purepac* decision, and the '482 patent with respect to which Purepac and TorPharm had both submitted paragraph IV certifications.

As to the former, the agency held that – in light of Pfizer's December 13, 2002 letter, this Court's decision in *Purepac*, and the Federal Circuit's decision in *Warner-Lambert* – the '479 patent should be withdrawn from the Orange Book. Together with the letter, those judicial decisions suggested that the '479 patent claimed only an unapproved use of the drug (the treatment of neurodegenerative diseases); however, FDA regulations specify that the Orange Book is reserved for patents relating to approved uses. *See* 21 C.F.R. § 314.53(b) ("For patents that claim a method of use, the applicant shall submit information only on those patents that claim indications or other

conditions of use of a pending or approved application."). The FDA had written Pfizer (which now owns Warner-Lambert's gabapentin patents and NDAs) to this effect on January 6, 2003. (A.R., tab 50.) On January 8, the company responded that, while it agreed that the '479 patent did not claim an approved use of gabapentin, the company would not withdraw the patent. Apparently, Pfizer was waiting for the Federal Circuit's decision, which issued on January 16; the next day, the company notified the FDA that it would at last remove the '479 patent from the Orange Book. (A.R., tab 60.)

Under applicable agency regulations, however, such a delisting would require all gabapentin ANDA applicants to withdraw any paragraph IV certifications and/or section viii statements they had made regarding that patent. *See* 21 C.F.R. § 314.94(a)(12)(viii)(B) ("If a patent is removed from the list, any applicant with a pending application (including a tentatively approved application with a delayed effective date) who has made a certification with respect to such patent shall amend its certification."). Moreover, once amended in this way, "the application will no longer be considered to be one containing a [paragraph IV] certification. . . ." *Id*. In other words, delisting the '479 patent would nullify all previous paragraph IV certifications to that patent. Accordingly, before removing the '479 patent from the Orange Book, the FDA had to determine whether any ANDA applicant was entitled to 180-day exclusivity with respect to that patent. (Fed. Defs.' Mem. in Opp. at 7.) If so, the agency could not delist until the end of that period before delisting. *See* 21 C.F.R. § 314.94(a)(12)(viii)(B) ("A patent that is the subject of a lawsuit under § 314.107(c) shall not be removed from the list until FDA determines either that no delay in effective dates of approval is required under that section as a result of the lawsuit, that the patent has expired, or that any such period of delay in effective dates of approval is ended."); *ANDA Rulemaking*, 59 FED. REG. at

50,348 ("[T]he agency has required that a patent remain on the list after being declared invalid or unenforceable until the end of any applicable 180-day exclusivity period.").

TorPharm argued that it was entitled to such exclusivity based on its certification to the '479 patent, and therefore that the FDA could not delist that patent until its exclusivity period expired. In its January 28 decision, however, the agency rejected this claim. The agency explained that Pfizer's letter, along with this Court's decision, as well as that of the Federal Circuit in *Warner-Lambert*, had made clear that the '479 patent did not in fact claim the use of treating epilepsy. And, because that was the sole use for which TorPharm's ANDA sought approval, a paragraph IV certification was not appropriate.[9/]

Moreover, if the '479 patent were to remain in the Orange Book, the agency held that TorPharm (along with all other applicants) would have been required to submit a section viii statement with respect to it. Here, the FDA reiterated its view that section viii statements and paragraph IV certifications are mutually exclusive alternatives: "An applicant does not have the option of making a paragraph IV certification in lieu of, or in addition to, a section viii statement; either the applicant is seeking approval for the use claimed in the patent, or it is not. The character of the patent and of the specific ANDA determine what the applicant must – and may – submit in response to a listed patent." (A.R., tab 18 at 4.) And because section viii statements do not confer exclusivity rights, no applicant,

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[9/] In reaching this conclusion, the FDA read 21 U.S.C. § 355(j)(2)(A)(vii) to mean that certifications (as opposed to section viii statements) are required only where the ANDA applicant is "seeking approval for a use claimed by a listed patent." (A.R., tab 18 at 4.) *Accord Warner-Lambert*, 316 F.3d at 1361 ("[A] certification need not be provided for a patent claiming a use for which the ANDA applicant is not seeking approval, *i.e.*, a use not covered by the NDA."). *But cf. Allergan*, 2003 WL 1572020, at *16 (Schall, J., concurring).

including TorPharm, would have been eligible for exclusivity based on the '479 patent. (*Id*.) From this it followed that 21 C.F.R. § 314.94 did not prevent the FDA from delisting the patent, which it did forthwith. All gabapentin applicants were therefore instructed to amend their ANDAs to withdraw any prior paragraph IV certifications or section viii statements regarding the '479 patent. (A.R., tab 19.)

Next, the FDA turned to the '482 patent. The agency determined that Purepac was the first applicant to submit an approvable ANDA containing a paragraph IV certification to this patent, and that as a result the company was entitled to a 180-day exclusivity period. The FDA reached this conclusion in the following way. There is no question that Purepac was the first applicant whose paragraph IV certification regarding the '482 patent was received by the FDA. This occurred on May 26, 2000, Purepac having mailed the certification the previous day.[10/] In contrast, the FDA did not receive TorPharm's certification, which was mailed on June 13, 2000, until June 16. (A.R., tab 18 at 6-7.) However, as noted above, when an ANDA is amended to include a paragraph IV certification, the applicant must also provide notice of that certification to the NDA holder and the patent owner. Purepac did so, but not at the same time that it sent its amendment to the FDA. Instead, Purepac waited until June 13, 2000 before mailing the required notice to Warner-Lambert. TorPharm, in contrast, sent its notice on the same day (June 13) that it mailed its certification to the agency.

Accordingly, there is no dispute that Purepac discharged its dual responsibilities with respect to the '482 patent (submitting a certification to the FDA and notifying the NDA holder/patent owner) before TorPharm. However, TorPharm's actions regarding this patent (unlike Purepac's) complied

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[10/] The FDA considers the operative date of a submission to be the date that it is *received* by the agency. (Fed. Defs.' Mem. in Opp. at 21 n.10.) Whether this policy is reasonable is considered *infra*.

with the letter of the statute, which mandates that the notice "shall be given *when* the amended application is submitted," 21 U.S.C. § 355(j)(2)(B)(iii) (emphasis added), and the implementing regulation, which provides that "the applicant shall send the notice required . . . *at the same time* that the amendment to the abbreviated application is submitted to FDA," 21 C.F.R. § 314.95(d) (emphasis added). TorPharm pointed this fact out to the FDA, and argued that Purepac's failure to abide by the statute should have voided its amendment. The agency, however, disagreed:

> Because Purepac did not give notice when it submitted the amendment to FDA, FDA will not treat the original receipt date as the relevant date for exclusivity purposes. Instead, the agency will look to the date that Purepac actually sent the required notice, since this is the date upon which Purepac effectively met the statutory requirements by having both submitted a paragraph IV certification and sent notice of the submission. This date is June 13, 2000.

(A.R., tab 18 at 6-7.) Thus, the FDA determined that the penalty for Purepac's failure to provide notice simultaneously with its certification should not be the nullification of that certification, but rather the postponement of the certification's effective date. And, because that date was still earlier than the effective date for TorPharm's certification, the agency concluded that only Purepac was eligible for 180-day exclusivity as to the '482 patent. (*Id*. at 7.)

TorPharm responded to the FDA's decision on January 31, 2003, when it wrote a letter contending that the agency's conclusion regarding the '479 patent could not be squared with the approach taken in a case involving a different drug, mirtazapine. There, the drug had been approved for the treatment of depression. Several generic manufacturers submitted ANDAs. The patent at issue, U.S. Patent No. 5,977,099 ("the '099 patent"), claimed the use of mirtazapine in combination with another kind of drug to treat depression. This was not an approved use of mirtazapine. It was not the

use for which the ANDAs sought approval. Nevertheless, all of the generic applicants submitted paragraph IV certifications to the '099 patent, and the FDA granted exclusivity to one of those applicants, Teva Pharmaceuticals, on the basis of that paragraph IV certification. Pointing to these facts, TorPharm argues that the mirtazapine case is on all fours with that of gabapentin, and if the FDA determined that Teva was entitled to paragraph IV-based exclusivity for the '099 patent, it represented unreasoned decisionmaking for the agency to refuse such exclusivity regarding the '479 patent. (A.R., tab 63.) The FDA did not have a chance to respond to this letter before TorPharm filed the instant action, along with its request for preliminary relief, on February 14, 2003. However, by letter dated February 24, 2003, the FDA rejected TorPharm's arguments regarding mirtazapine. (A.R., tab 65.)

The Court subsequently invoked Rule 65(a)(2) to consolidate the preliminary injunction hearing with a final decision on the merits.[11/] The analysis that follows therefore focuses solely on the merits of TorPharm's argument that the FDA violated the Administrative Procedure Act ("APA"), 5 U.S.C. § 701 et seq., when it determined that TorPharm was not entitled to 180-day exclusivity with respect to either the '479 patent or the '482 patent.

ANALYSIS

I. Exclusivity Regarding the '482 Patent

TorPharm first argues that it is entitled to exclusivity as to the '482 patent because it was the first ANDA applicant to actually comply with the statutory mandate that notice shall be provided to the

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[11/] The Court also granted a motion filed by Teva Pharmaceuticals USA, Inc. to appear as *amicus curiae* in this action.

NDA holder (and patent owner) *at the same time* that the applicant amends its application to include a paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B)(iii). TorPharm is correct about what the statute requires, but wrong about what it believes to be the necessary consequences of Purepac's non-compliance.

As recounted above, the relevant dates here are as follows. Purepac's paragraph IV certification regarding the '482 patent was received by the FDA on May 26, 2000. The company then sent its notice to Waner-Lambert on June 13, 2000. In contrast, TorPharm sent its certification and notice on the same day, June 13, 2000, but the certification was not received by the FDA until June 16. The critical question here, then, is what follows from the fact that Purepac, unlike TorPharm, did not provide notice to Warner-Lambert at the same time that it offered its amended certification to the FDA. In doing so, Purepac did not strictly abide by the terms of the statutory provision quoted above or the FDA regulation implementing that provision.[12/] *See* 21 C.F.R. § 314.95(a)(1). TorPharm now contends that Purepac's disobedience necessitates the nullification of its paragraph IV certification. (TorPharm's Mem. at 16, 18.) There is, however, nothing in the FDCA itself that actually compels, or even suggests, such a harsh result. The statute is in fact silent on the issue of what follows from an applicant's failure to follow the mandate of simultaneity.

As such, the agency had considerable flexibility in deciding what the appropriate consequence of such a violation should be. Indeed, as has long been recognized in this Circuit, "the breadth of an

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[12/] As did the FDA, the Court rejects Purepac's suggestion that it "substantially complied" with the notice provision. (A.R., tab 18 at 7.) The statute and regulation both say that the notice and certification must be provided at the same time. By any measure, sending notice two and a half weeks after the certification represents *non*-compliance with this requirement.

agency's discretion is, if anything, at its zenith when the action assailed relates primarily not to the issue of ascertaining whether conduct violates the statute, or regulations, but rather to the fashioning of policies, remedies and sanctions. . . ." *Niagra Mohawk Power Corp. v. FPC*, 379 F.2d 153, 159 (D.C. Cir. 1967); *see also Connecticut Valley Elec. Co. v. FERC*, 208 F.3d 1037, 1044 (D.C. Cir. 2000) ("In other words, the Commission ordinarily has remedial discretion, even in the face of an undoubted statutory violation, unless the statute itself mandates a particular remedy."); *cf. Butz v. Glover Livestock Conm'n Co.*, 411 U.S. 182, 185-86 (1973) (noting the fundamental principle that "where Congress has entrusted an administrative agency with the responsibility of selecting the means of achieving the statutory policy the relation of remedy to policy is peculiarly a matter for administrative competence") (internal quotation marks omitted); *Porter County Chapter v. NRC*, 606 F.2d 1363, 1369 (D.C. Cir. 1979) ("Generally speaking, the law gives agencies wide discretion to determine the means of administration of pertinent regulatory standards, the techniques of interpretation, application, filling in of details, and enforcement. The agency is not bound to launch full-blown proceedings simply because a violation of the statute is claimed.").

Here, the FDA has exercised that discretion reasonably. In its Decision Letter, the agency determined that where a certification is submitted without simultaneous notice, that certification does not become effective for exclusivity purposes until the notice is actually sent. In other words, where notice is provided after the certification is received, the agency's policy constructively moves the certification's "submission" date to the day on which the applicant mailed the notice. This approach does not, as TorPharm argues, "ignore" or "waive" the requirements of the notice provision. (TorPharm's Mem. at 17-18.) Rather, it acknowledges that notice and certification must occur together, and therefore

refuses to give legal recognition to one act until the other has been effectuated as well. As such, the agency's policy does not create the "reward" for non-compliance that TorPharm ominously invokes (TorPharm's Mem. at 21), but instead punishes an applicant's failure to furnish simultaneous notice by refusing to make its solitary certification immediately effective upon receipt by the agency. Those who heed the notice provision reap the benefit of instant acceptance; those who do not, do not.

As such, Purepac's actions did not "game" the system, as the company secured no unfair advantage by submitting a premature certification. Because the FDA delayed the operative date of Purepac's certification to the date that notice was sent to Warner-Lambert, the company ultimately gained nothing by splitting the two acts in derogation of the statutory directive. While this punishment is perhaps not the draconian sanction that TorPharm favors, the choice of sanction is the agency's to make, and TorPharm has pointed to nothing in the Hatch-Waxman Amendments that specifically (or even impliedly) mandates that every violation of the notice provision automatically renders a certification null and void.[13/] Accordingly, the FDA acted reasonably in concluding that Purepac's paragraph IV certification to the '482 patent need not be discarded merely because Purepac did not provide simultaneous notice.

With this objection out of the way, the only remaining question is whether the FDA properly construed the statute to make the operative date (assuming notice has been sent) for the filing of an

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[13/] Moreover, as Purepac points out, there is at least one other consequence for an ANDA applicant who provides tardy notice. Under 21 U.S.C. § 355(j)(5)(B)(iii), the 45-day period that the patent owner has to bring an infringement action based on the paragraph IV certification does not begin to run until the owner receives notice. (Purepac's Mem. in Opp. at 22-23.) Because the ANDA cannot be approved until this period has expired, the applicant who does not provide notice at the same time as it makes its amended certification succeeds only in delaying its own opportunity to begin marketing the generic drug.

amended certification the day the certification is *received* by the agency, rather than the day the certification is *mailed* by the applicant. TorPharm argues that this interpretation is unreasonable. The question is important here because if the mailing date instead controlled, Purepac and TorPharm would have executed their dual obligations on the same day (June 13, 2000) the date on which the former sent its notice to Warner-Lambert and the latter sent its certification to the FDA. It is only because the agency treated the effective date of TorPharm's certification as the date that the amendment was actually received (June 16) that Purepac's certification was deemed to have been filed first. The Court believes that the FDA's approach was reasonable.

To begin with, TorPharm points to nothing in the statute that precludes the FDA's date-of-receipt rule, or that mandates an alternative mailbox rule. While it is true that 21 U.S.C. § 355(j)(2)(B)(ii) speaks only about when an amended certification is "submitted," this is hardly dispositive. The agency could have reasonably construed the word "submitted" to support the rule that it has chosen. When used in the sense that it is used here, "submit" implies action on the part of the party to whom the submission has been made. *See* OXFORD ENGLISH DICTIONARY (defining "submit" as "to refer to the decision or judgement of a person"). It follows therefore that the time of submission can be understood to refer to the time when that party is actually in a position to take the relevant action, which is at the moment of actual receipt. *See, e.g., Monark Boat Co. v. NLRB*, 708 F.2d 1322, 1329 (8th Cir. 1983) ("The Board could reasonably conclude that an application has not been submitted until it is possible for the Board to act on the application – that is, when the Board receives the application.").

More important, however, is the fact that § 355(j)(2)(B)(ii) does not purport to govern when a

paragraph IV amendment actually becomes effective for exclusivity purposes. Instead, it declares only that notice of the amendment shall be given when the amendment is submitted (however that is defined) to the agency. As such, the notice provision simply does not speak to the question here, which is whether the sending date or the receiving date controls in determining when an amended paragraph IV certification should be recognized as part of the ANDA in order to determine which applicant is entitled to 180-day exclusivity. For that, the relevant text is § 355(j)(5)(B)(iv), which speaks only of a "previous application," without providing any guidance for how to establish that nebulous distinction. Nor do any of the regulations cited by the parties actually govern this issue. *See, e.g.*, 21 C.F.R. § 10.20(e) (general rule for FDA

docket submissions); 21 C.F.R. § 314.100(a) (timeframes for reviewing NDAs and ANDAs); 314 C.F.R. § 314.101(a)(2) (same).

In the face of such statutory and regulatory silence, the approach adopted by the FDA is permissible. As the agency points out, its date-of-receipt rule has the benefit of clarity. "If FDA were to rely on the date the application or amendment was sent, for instance, it could lead to potential confusion and ambiguity with respect to differences between the date on the submission itself, and the date it is post-marked or provided to a delivery service." (Fed. Defs.' Mem. in Opp. at 25.) It is well within the FDA's administrative discretion to adopt this sort of reasonable "housekeeping" rule to make it easier for the agency to determine the order in which amended paragraph IV certifications are filed. *Cf. JEM Broad. Co. v. FCC*, 22 F.3d 320, 328 (D.C. Cir. 1994) (holding that such rules can be adopted without the benefit of notice and comment). Because this choice is a reasonable one, and is not precluded by statute or by regulation, the Court will not disturb the FDA's policy of considering an

amendment as having been effectively submitted at the time it was received.

For these reasons, the agency reasonably determined that Purepac was the first applicant to offer an effective paragraph IV certification to the '482 patent, and therefore properly awarded 180-day exclusivity to Purepac based on that patent.[14/]

II. Exclusivity Regarding the '479 Patent

Next, the Court must consider whether the FDA correctly decided that no ANDA applicant was eligible for 180-day exclusivity based on the '479 patent. As described above, on remand from this Court's decision in *Purepac* the FDA decided that the '479 patent should be removed from the Orange Book. Under agency regulations, however, because that patent had been the "subject of a lawsuit" based on a paragraph IV certification, it could be delisted only if no ANDA applicant was, at the time of delisting, entitled to exclusivity based on that patent. 21 C.F.R. § 314.94(a)(12)(viii)(B). The question here is whether the FDA correctly determined that, in the wake the *Purepac* decision, TorPharm could no longer maintain its paragraph IV certification to the '479 patent or, even if it could, whether that certification would have actually prohibited the agency from approving any rival ANDAs until the end of the exclusivity period. If not, the agency acted properly in ordering the patent removed from the book.

As to whether TorPharm was still entitled to its paragraph IV certification, the FDA's concluded that – in light of *Purepac*, as well as the Federal Circuit's decision in *Warner-Lambert* and

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[14/] In light of this conclusion, the Court need not address Purepac's argument that the notice provision is entirely irrelevant to the exclusivity provision, and therefore that exclusivity should be based solely on the first submission of a paragraph IV certification without regard to whether the ANDA applicant has provided notice to the NDA holder. (Purepac's Mem. in Opp. at 12-17.)

Pfizer's December 13 letter – a section viii statement, rather than a paragraph IV certification, was appropriate for the '479 patent. (A.R., tab 18 at 4-5.) While the Court is concerned about the Decision Letter's references to *Warner-Lambert*,[15/] this unfortunate aspect of the letter does not require that the agency's decision be vacated. For, despite the haze created by the letter's imprecise language, the Court can readily "discern the path" that the agency intended to travel. *See Bowman Transp., Inc. v. Arkansas-Best Freight Sys*., 419 U.S. 281, 286 (1974) (court "will uphold a decision of less than ideal clarity if the agency's path may be reasonably discerned"). And, because the FDA's conclusion comfortably and correctly rests on that basis, reversal and remand are not required. *See FEC v. Legi-Tech, Inc*., 75 F.3d 704 708-09 (D.C. Cir. 1996) (affirming the proposition that "remand to the agency is an unnecessary formality where the outcome is clear"); *Am. Fed. of Gvm't Employees v. Fed. Labor Relations Auth.*, 778 F.2d 850, 862 n.19 (D.C. Cir. 1985) (citing cases for this proposition); *NLRB v. Am. Geri-Care, Inc.*, 697 F.2d 56, 64 (2d Cir. 1982) (holding that even where the agency assigns the wrong reason for its actions, reversal and remand are required "*only* where there is a significant chance that but for the error, the agency might have reached a different

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[15/] As TorPharm points out, reliance on that decision would be problematic for the following reason. If a judicial determination of non-infringement in patent litigation triggered by the use of a paragraph IV certification comes to serve as the basis for a subsequent FDA determination that the patent in question should no longer be listed – and therefore that a paragraph IV certification, and its corresponding promise of exclusivity, is no longer appropriate – the incentive structure created by the Hatch-Waxman Amendments would be turned on its head. The purpose of the paragraph IV mechanism is to give generic manufacturers an incentive (the 180-day exclusivity) to risk pre-approval patent litigation in order to get generic drugs on the market quickly. As such, the fruits of a paragraph IV lawsuit should not supply the fodder for a later determination that paragraph IV should not have been used in the first place. It would be cruelly ironic, and quite perverse, to use an ANDA applicant's *success* in such an infringement action as the basis for *denying* exclusivity to that applicant. And, indeed, the purpose of the delisting regulation is to avoid this perversion.

result").

As noted above, the FDA has long taken the position that paragraph IV certifications and section viii statements are mutually exclusive. In *Purepac*, the Court called attention to this view, but observed:

> [A]t oral argument, the agency stated that it has not taken a definitive position as to whether equitable considerations might ultimately persuade it to allow two applicants to submit a certification and a statement, respectively, with respect to the same patent. As such, the FDA has not decided whether it could, or would, approve TorPharm's application with a paragraph IV certification to the '479 patent even if the Court were to direct the agency to accept Purepac's application with a section viii statement.

238 F. Supp. 2d at 211. Allowing the agency to make this decision was in fact the very purpose for which the case was remanded. In this light, the Court reads the Decision Letter as ultimately expressing the FDA's view that whatever equities may exist in this case, they were not sufficiently compelling to persuade the agency to make an exception to its well-established position that where a section viii statement is appropriate, a paragraph IV certification is not. This is reflected in the Decision Letter's insistence that an "applicant does not have the option of making a paragraph IV certification in lieu of, or in addition to, a section viii statement; either the ANDA applicant is seeking approval for the use claimed in the patent, or it is not." (A.R., tab 18 at 4.)

In other words, then, once this Court had decided that Purepac could use a section viii statement – a substantive conclusion with which the Decision Letter signals agreement (A.R., tab 18 at 4-5) – the agency found no reason to depart from its rule and allow any other applicant to maintain a

paragraph IV certification.[16/] Refusing to make an equitable exception from this rule was within the FDA's discretion, and TorPharm has pointed to nothing in the statute or regulations to cast doubt on the rule itself. Moreover, even if that rule has not been embodied in a formal regulation, it is still entitled

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[16/] It should be noted that the facts relied upon by this Court to support its holding did not relate to the infringement litigation between Warner-Lambert and TorPharm. Instead, the Court's decision was based on information available to the FDA and the generic applicants at the time the original ANDAs were submitted. As such, the problems discussed in the previous footnote do not arise in this context. None of the information that TorPharm helped bring to light as a result of making its certification to the '479 patent was used against it by this Court in determining that Purepac's section viii statement was proper. Thus, insofar as the FDA relied on the *Purepac* decision in concluding that TorPharm could no longer maintain its paragraph IV certification, TorPharm's concerns about vitiating the rewards intended for applicants who prevail in patent infringement litigation are beside the point.

Moreover, TorPharm's argument that the FDA erred by applying the *Purepac* decision retroactively fails both as a matter of fact and law. In the Decision Letter, the agency determined merely that, in light of the holding in *Purepac*, TorPharm could no longer maintain a valid paragraph IV certification to the '479 patent. As such, the agency was regulating prospectively; it was not passing judgment on previous actions taken by TorPharm, but rather was applying the reasoning and result of the Court's decision to sort out which gabapentin applicant would be given *future* exclusivity privileges. In so doing, the FDA resolved the one question that the Court had left undecided, and indeed had specifically reserved for the agency to resolve on remand. It is thus simply wrong to characterize that resolution as a retroactive one.

Further, even if the agency's decision could be characterized as applying retroactively, it would not constitute a violation of the APA. While the decision may have undermined TorPharm's reliance on the agency's previous assurances that a paragraph IV certification to the '479 patent was acceptable, this does not provide grounds for reversal in the circumstances presented here. For, as the D.C. Circuit has recently held, "administrative agencies have greater discretion to impose their rulings retroactively when they do so in response to judicial review, that is, when the purpose of retroactive application is to rectify legal mistakes identified by a federal court." *Verizon Tel. Cos. v. FCC*, 269 F.3d 1098, 1111 (D.C. Cir. 2001). Thus, where an agency's assurances about the law are subsequently undermined through the process of judicial review, it is clear that the agency may rectify its original mistake without concern about retroactivity. The fact that one party may have relied on that mistake does not render its belated correction unlawful, at least (as here) where the correction comes in direct response to the decision of a federal court. *See id*. at 1111-12. Thus, insofar as the FDA relied on this Court's holding that Purepac's section viii statement to the '479 patent was proper in reaching its determination that no other applicant could maintain a paragraph IV for that patent, *Verizon* leaves the agency's determination immune from attack on retroactivity grounds.

to judicial deference in the absence of some indication that it conflicts with any of the constraints on the agency's regulatory authority, is inconsistent with the agency's own prior pronouncements, or is otherwise poorly reasoned or unpersuasive. *See United States v. Mead Corp*., 533 U.S. 218, 234-35 (2001) (holding that even informal agency interpretations not entitled to *Chevron* deference are nonetheless entitled to some "persuasive force") (citing *Metropolitan Svetedore Co. v. Rambo*, 521 U.S. 121, 136 (1997)). There are no such indications here.

From this conclusion, the rest of the agency's actions follow readily. Once TorPharm's paragraph IV certification was deemed improper in light of Purepac's section viii statement, which the FDA was compelled to accept, the agency had two options. First, it could have required TorPharm to submit its own section viii statement to replace the rejected paragraph IV. Alternatively, it could have done as it did and removed the patent from the Orange Book altogether, for the prospect of exclusivity on the '479 patent had been vitiated by the determination that TorPharm could no longer use a paragraph IV certification, and the delisting regulation posed no impediment to striking the patent from the agency's records. For exclusivity purposes, however, there is no functional difference between these options, for either way TorPharm's claim to exclusivity based on the '479 patent is extinguished.[17/] Accordingly, because the Court finds that the FDA acted reasonably in not departing from its well-settled rule that a section viii statement and paragraph IV certification cannot be filed as to the same patent, the agency's corresponding conclusion that no applicant was entitled to exclusivity on

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[17/] As such, TorPharm can get no closer to eligibility for exclusivity based on the '479 patent by attacking the delisting decision unless it can also show, which it cannot, that the FDA's (perhaps more straightforward) alternative would have been impermissible as well.

the '479 patent must be upheld as well.[18/]

Finally, the Court rejects TorPharm's argument that the FDA's disallowance of the paragraph IV certification was inconsistent with the agency's actions regarding certifications made by ANDA applicants in the case of the drug mirtazapine. (TorPharm's Mem. at 26-28.) Whatever similarities may exist between the circumstances of mirtazapine and those of gabapentin, one crucial difference remains: in the former case, there was no court decision requiring the FDA to accept a section viii statement with respect to the patent in question. Thus, in deciding what to do there, the agency's regulatory role was not constrained, as it was here, by an injunction requiring it to accept the section viii statement submitted by one applicant. Accordingly, the fact that the agency allowed the mirtazapine applicants to use paragraph IV certifications to a method-of-use patent that did not claim an approved use of the drug does not compel the agency to do the same in this case. Whatever the merits of the

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[18/] In light of the Court's conclusion that the FDA appropriately rejected TorPharm's bid to keep its paragraph IV certification to the '479 patent, it is not necessary to dissect the thornier issue of whether TorPharm would have been entitled to exclusivity even if it had been permitted to retain its paragraph IV certification. To this end, TorPharm argues that an ANDA applicant has a legitimate claim to 180-day exclusivity even where it is the only applicant to submit a paragraph IV certification for a particular patent. (TorPharm's Reply Br. at 23.) While the Court does not need to reach this question, it does note that the result urged by TorPharm appears to be foreclosed by the FDA's regulation governing exclusivity. This regulation makes clear that a subsequent ANDA is blocked from approval *only* if it contains a paragraph IV certification, and a previous applicant has already submitted an application containing a paragraph IV certification *to that same patent*. *See* 21 C.F.R. § 314.107(c)(1). Given the existence of the regulation, even if TorPharm could demonstrate that the FDA abused its discretion when it stripped the company of its paragraph IV certification, it is still unlikely that TorPharm would thereby have a claim to exclusivity based on the '479 patent, since Purepac never submitted a corresponding paragraph IV certification to that patent. Therefore, in order to prevail in its bid for exclusivity, at least as against Purepac, TorPharm would have to demonstrate that the FDA's regulation is somehow unreasonable or contrary to the underlying statute, which is generally an onerous task, and would likely be so here as well.

agency's determination regarding the '099 patent, that determination certainly does not stand for the proposition that the FDA will allow one generic applicant to use a section viii statement while allowing another applicant to use paragraph IV certification to the same patent.

And, while TorPharm is correct that this Court's opinion in *Purepac* did not, by its terms, *compel* the FDA to reject the paragraph IV certification (TorPharm's Reply Br. at 20-21), this hardly means that the *Purepac* decision is irrelevant in distinguishing gabapentin from mirtazapine. The reason that the Court did not take that step was that the agency had not yet made a final decision whether it would, or could, make an exception to its general rule that section viii and paragraph IV are mutually incompatible. While the Court took note of this window, it did not instruct the agency to leave it open. The FDA's subsequent decision to definitively slam it shut was thus entirely consistent with the Court's remand order. And, once the agency decided that its long-standing rule *would* apply, a decision that TorPharm has not shown to be unreasonable, it followed inexorably from the terms of the Court's injunction that TorPharm would be required to withdraw its certification. As such, the *Purepac* decision is sufficient to distinguish the result reached in the Decision Letter from the conclusions the agency reached with respect to mirtazapine. The mere fact that paragraph IV certifications were permitted there provides no basis for requiring the FDA to allow them here.

CONCLUSION

For the reasons given above, the FDA's conclusion that Purepac was the first ANDA applicant to submit an effective paragraph IV certification to the '482 patent was reasonable. So too was the agency's determination that no applicant was entitled to submit a paragraph IV certification to the '479

patent. Accordingly, the agency properly held that Purepac, and Purepac alone, is entitled to 180-day exclusivity to market a generic version of gabapentin.

ELLEN SEGAL HUVELLE
United States District Judge

DATE: April 25, 2003

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TORPHARM, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
TOMMY G. THOMPSON, *et al*.	)	
	)	
Defendants,	)	**Civil Action No. 03-0254 (ESH)**
	)	
and	)	
	)	
PURPAC PHARMACEUTICAL CO.,	)	
	)	
Intervenor-Defendant	)	
	)	

ORDER

For the reasons given in the attached Memorandum Opinion, it is hereby

ORDERED that plaintiff's motion for a preliminary injunction is **DENIED**; and it is

FURTHER ORDERED that final judgment shall be entered in favor of defendants.

IT IS SO ORDERED.

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ELLEN SEGAL HUVELLE
United States District Judge

DATE: April 25, 2003